App. No. 10/501,291
Office Action Dated March 24, 2008

REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 1, 6, 9, 13-15, 17, 20 and 24 have been amended. The amendments to claim 1 are supported by the original specification, for example by page 3, lines 16-22 and Example 1 on page 52, line 25 to page 53, line 30. The amendments to claim 6 are supported by the original specification, for example by page 7, lines 31-33. The amendments to claim 9 are supported by the original specification, for example by page 3, lines 16-22 and Example 1 on page 52, line 25 to page 53, line 30. Claims 13-15, 17, 20 and 24 have been amended editorially. Claim 12 has been canceled without prejudice or disclaimer. Claims 1-2, 4-11 and 13-30 are pending. No new matter has been added.

Claim rejections - 35 U.S.C. § 103

Claims 1, 2 and 4-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP1 002874 A2 (Komori et al.) in view of Biochemistry, 1988, Vol. 27, pp. 5470-5476 (Montellano et al.) and further in view of US Patent No. 6,127,138 (Ishimaru et al.), and further in view US Patent No. 5,556,788 (Kwan et al.). Applicants respectfully traverse this rejection.

Claim 1 is directed to a method of measuring an amount of a glycated protein as an analyte in a sample. Claim 1 requires adding a FAOD for degradation (degradation FAOD) to the sample as a pretreatment so that a glycated amino acid as a contaminant present in the sample is degraded and removed from the sample by the degradation FAOD and the analyte remains in the sample, adding a protease to the sample to give a degradation product of the analyte remaining in the sample, adding a FAOD for measurement (measurement FAOD) to the sample treated with the protease to cause a redox reaction between the measurement FAOD and the degradation product of the analyte, and measuring an amount of hydrogen peroxide generated by the redox reaction to determine the amount of the analyte. Claim 1 further requires the measurement FAOD to be added after the step of adding the protease to the sample.

The rejection contends Komori teaches the analyte is glycated amino acid and the glycated amino acids are subject to the action of FAOD. However, nothing in the reference teaches or suggests adding a degradation FAOD as a pretreatment so that glycated amino acid as a contaminant present in the sample is degraded and removed from the sample by the

degradation FAOD while the glycated protein as the analyte remains in the sample before the measurement step, and thereafter, adding a measurement FAOD to the sample treated with the protease to cause a redox reaction between the measurement FAOD and the degradation product of the glycated protein resulting from the protease treatment. Therefore, claim 1 and the dependent claims are patentable over Komori for at least these reasons.

Claim 9 is directed to a measuring kit. Claim 9 requires the measuring kit to include a a protease reagent containing a protease. Claim 9 requires the measuring kit to further include a pretreatment reagent that contains a first fructosyl amino acid oxidase that is present in an amount suitable for the degradation of a glycated amino acid as a contaminant present in the sample, and a separate color-developing reagent that contains a second fructosyl amino acid oxidase that is present in an amount suitable for the redox reaction with the degradation product of the analyte degraded by the protease.

The rejection contends that there would have been a reasonable expectation of success at the time the invention was made to combine the steps of the method of measuring an amount of glycated protein taught by Komori in an apparatus that was recited by Ishimaru. However, nothing in the references teaches or suggests using a pretreatment reagent containing a first FAOD that is present in an amount suitable for the degradation of a glycated amino acid as a contaminant present in the sample, and a separate color-developing reagent that contains a second FAOD that is present in an amount suitable for the redox reaction with a degradation product of the analyte degraded by the protease. Accordingly, claim 9 and the dependent claims therefrom are patentable over the references, taken alone or separately.

Double Patenting

Claims 1-30 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent No. 6,790,665 (Yonehara). Applicants respectfully traverse the rejection.

Claims 1-22 of Yonehara recite a method where FAOD is used to generate hydrogen peroxide from a degraded glycated protein, which includes glycated amino acid derived from the glycated protein. However, the claims fail to recite the steps of adding a degradation FAOD as a pretreatment so that glycated amino acid as a contaminant present in the sample is degraded and removed from the sample by the degradation FAOD while the glycated protein as the analyte remains in the sample, and thereafter, adding a measurement FAOD to the

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sample treated with the protease to cause a redox reaction between the measurement FAOD and the degradation product of the glycated protein resulting from the protease treatment so as to determine the amount of the glycated protein. Therefore, claim 1 and the dependent claims therefrom of the present application are patentable over Yonehara. Furthermore, Yonehara fails to recite or suggest a measuring kit having a pretreatment reagent containing a first FAOD that is present in an amount suitable for the degradation of a glycated amino acid as a contaminant present in the sample, and a separate color-developing reagent containing a second FAOD that is present in an amount suitable for the redox reaction with the degradation product of the analyte degraded by the protease. Therefore, claim 9 and the dependent claims therefrom of the present application are patentable over Yonehara.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Dated: August 25, 2008

Respectfully submitted,

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